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(54) **DIALYSIS MACHINE HAVING A DEVICE FOR SENSING THE DETACHMENT OF THE VENOUS NEEDLE FROM A PATIENT DURING AN EXTRACORPOREAL BLOOD TREATMENT**

DIALYSEMASCHINE MIT EINER VORRICHTUNG ZUR ERFASSUNG DER ABTRENUNG DER VENÖSEN NADEL VON EINEM PATIENTEN WÄHREND DER EXTRAKORPORALEN BLUTBEHANDLUNG

MACHINE DE DIALYSE AVEC UN DISPOSITIF POUR DETECTER LA SORTIE DE L'AIGUILLE DE LA VEINE D'UN PATIENT PENDANT UN TRAITEMENT EXTRACORPOREL DU SANG

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(73) Proprietor: **Gambro Lundia AB**
22 643 Lund (SE)

(72) Inventors:
• **LODI, Carlo, Alberto**
I-41016 Novi di Modena (IT)

• **PAOLINI, Francesco**
I-41010 Ganaceto (IT)
• **CANINI, Enrico**
I-41037 Mirandola (IT)

(74) Representative: **Villanova, Massimo**
Gambro Intellectual Property Department,
P.O. Box 98
41037 Mirandola (MO) (IT)

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WO-A-99/24145 **FR-A- 2 067 572**

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Description

[0001] The present invention relates to a dialysis machine comprising a device for sensing the access to a patient's cardiovascular system during an extracorporeal blood treatment in a dialysis machine.

[0002] As is known, blood consists of a liquid component called the blood plasma and a corpuscular component formed by the blood cells, including the red corpuscles among other components. In renal insufficiency, the blood has, in addition to the aforesaid components, particles of low molecular weight (referred to below as solute) which have to be eliminated by a dialysis treatment carried out with a dialysis machine.

[0003] A dialysis machine of the known type generally comprises an extracorporeal blood circuit, a dialysate circuit and a filter, which is located in the aforesaid circuits and comprises a blood compartment and a dialysate compartment, which are separated from each other by a semi-permeable membrane, and through which pass, respectively, the blood to be treated and the dialysate, generally flowing in counter-current mode.

[0004] During the dialysis treatment, the undesired particles contained in the blood migrate from the blood compartment to the dialysate compartment through the semi-permeable membrane both by diffusion and by convection, as a result of the passage of some of the liquid contained in the blood towards the dialysate compartment. Thus the patient will have lost some weight by the end of the dialysis process.

[0005] The extracorporeal circuit is connected to the patient by means of an arterial needle and a venous needle, which are inserted into a fistula formed in the patient's cardiovascular system, so that they can, respectively, collect the blood to be treated and return the treated blood to the patient's cardiovascular system. The extracorporeal circuit comprises, in addition to the filter located between the venous branch and the arterial branch, a peristaltic pump and a dropper located in the arterial branch and in the venous branch respectively. The detachment of one of the aforesaid needles from the fistula causes an interruption of the access to the patient's cardiovascular system. The detachment of the venous needle, if not detected in good time, has particularly serious consequences, because it can cause a significant blood loss in the patient. Various attempts have therefore been made to provide methods for sensing the detachment of the aforesaid needles, and particularly of the venous needle.

[0006] One of the aforesaid known methods is described in WO 99/12588. This method is based on the electrical conductivity of the blood, and consists of the injection of a current into a closed circuit consisting of the extracorporeal circuit and the patient's cardiovascular system, and the measurement, by means of a measuring instrument located in the aforesaid extracorporeal circuit, of the current variations which are caused by the detachment of one or both of the needles. In this method,

the current injection and the measurement of the current variation have to be carried out by inductive coupling, in other words by means of windings located at specified points along the extracorporeal blood circuit.

[0007] The method described above has various drawbacks. In particular, this method, although theoretically valid, cannot provide satisfactory results from the practical point of view, since the high electrical impedance produced by the peristaltic pump, which effectively interrupts the continuity of the blood flow, makes it necessary to operate with relatively high currents in order to make use of the low conductivity of the materials, generally PVC, which are used to form the extracorporeal circuit, the filter, the peristaltic pump and the dropper. The use of relatively high currents cannot be recommended for safety reasons in a machine connected to a patient, and, even if they could be used, it would not be possible to transmit these high currents by means of an inductive coupling, which, among other considerations, also generates parasitic currents which interfere with the measurement. In some dialysis machines, the dropper also creates a high impedance, of the same order of magnitude as that created by the peristaltic pump, and thus exacerbates one of the problems described above.

[0008] Consequently, because there is a requirement to operate with relatively low currents, and because the impedance of the peristaltic pump, and of the dropper in most cases, is high, the detachment of one of the needles causes current variations which are not easily identifiable and which can be confused with the background noise of the measuring instrument.

[0009] Furthermore, this method does not allow for the fact that the patient may be connected to earth and that the filter itself is necessarily connected to earth, since the dialysate circuit is connected to earth to meet the requirements of the safety regulations for dialysis machines. Therefore the electrical circuit assumed in the aforesaid application does not truly represent the real analogy of a dialysis machine in electrical terms.

[0010] The object of the present invention is to provide a dialysis machine comprising a device for sensing the detachment of the venous needle from a patient during an extracorporeal blood treatment in a dialysis machine, which overcomes the drawbacks of the prior art.

[0011] According to the present invention, a dialysis machine is provided comprising a device for sensing the detachment of the venous needle from a patient during an extracorporeal blood treatment according to claims 1 or 2.

[0012] To enable the present invention to be more clearly understood, a preferred embodiment of it will now be described, purely by way of example and without restrictive intent, with reference to the attached figure, which is a schematic view of a dialysis machine connected to a patient and fitted with a device for sensing the detachment of the venous needle according to the present invention.

[0013] In the attached figure, the number 1 indicates

the whole of a dialysis machine connected to a patient P. The machine 1 comprises an extracorporeal blood circuit 2, a dialysate circuit 3 and a filter 4, which comprises a blood compartment 5 and a dialysate compartment 6 separated by a semi-permeable membrane 7.

[0014] The extracorporeal blood circuit 2 comprises, in addition to the aforesaid compartment 5 of the filter 4, an arterial branch 8, in which is located a peristaltic pump 9 providing a flow Q_b of blood, and a venous branch 10, in which is located a dropper 11. The branch 8 has an arterial needle 12, which, when in use, is inserted into a fistula (not shown) in the patient P to collect the blood from the cardiovascular system of the patient P, while the branch 10 has a venous needle 13, which, when in use, is inserted into the aforesaid fistula to return the treated blood to the cardiovascular system of the patient P. The branches 8 and 10 are tubes made from plastic material, generally PVC, and are used, respectively, to supply the blood to be treated to the compartment 5 and to introduce the treated blood leaving the compartment 5 into the cardiovascular system. The filter 4 and the dropper 11 are also made from plastic material, generally PVC.

[0015] The machine 1 is fitted with a device 14 for sensing the detachment of the venous needle 13. The operation of the device 14 is based on the electrical conductivity of the blood and on experimental measurements which have demonstrated that the material used to form the circuit 2, generally PVC, can be considered to be an insulator, and that both the peristaltic pump 9 and the dropper 11 can be considered to be concentrated impedances indicated by Z1 and Z2 respectively. The peristaltic pump 9 causes a cyclic interruption in the flow of blood at every half revolution of the pump 9 and thus the impedance Z1 is a function of the number of revolutions of the pump 9 and of the power supply frequency. Experimental tests have shown that the impedance Z1 is in the range from 500 to 2000 k Ω . The impedance Z2 is also determined by the fact that the blood flow Q_b is interrupted at the dropper 11 and the value of Z2 is also in the range from 500 to 2000 k Ω .

[0016] The impedances of the other components of the extracorporeal circuit 2 are negligible with respect to the values of the impedances Z1 and Z2.

[0017] The device 14 comprises a control unit 15, a voltage generator 16, a voltage drop sensor 17, an electrical line 18, a transformer 19 comprising a primary 20 and a secondary 21. The voltage generator 16 sends a current along the line 18, which is connected to the primary 20 of the transformer 19, while the secondary 21 of the transformer forms a branch 22 connectable to the venous branch 10 and with a branch 23 connected to earth. The branch 23 comprises a concentrated impedance Z3 and is connected to the voltage sensor 17, which detects the voltage across the terminals of the impedance Z3. A three-way selector 24 is located in the branch 22 to interrupt the current along the branch 22 and selectively connect the secondary 21 of the transformer 19

to the venous branch 10 when the selector 24 is in the position A (shown by a broken line), to a branch 25 when the selector 24 is in the position B (shown by a solid line), and to a branch 26 when the selector 24 is in the position C (shown by a chain line). The branches 25 and 26 are connected to earth and have impedances of Z4 and Z5 respectively. The sensor 17 is connected to the unit 15, which processes the voltage signal and comprises a rectifier 27 which receives at its input the signal from the sensor 17 and supplies at its output a rectified signal, a mean value sensor 28 which has the rectified signal at its input and a mean value signal at its output, an adder 29 having the mean value signal at its input and an added signal at its output, a band-pass filter 30 having the added signal at its input and a filtered signal at its output, and a comparison unit 31 which compares the filtered signal with a threshold value and emits at its output a signal for controlling an integrator 32 connected to a comparison unit 33, which receives at its input the signal emitted by the integrator 32, compares the signal of the integrator 32 with a threshold value, and emits a control signal.

[0018] The dialysis machine 1 comprises a control unit 34, which is connected to the control unit 15 of the device 14 to receive the control signal, and to the peristaltic pump 9.

[0019] The branch 22 is formed by an electrical conductor, while the venous branch 10 is formed by a tube of plastic material, in which blood circulates when the machine is in use. The branch 22 and the venous branch 10 are electrically coupled by an electrode 35, which comprises a ring 36 placed around the venous branch 10 at a point lying, between the dropper 11 and the venous needle 13. The electrode 35 may alternatively be defined by a number of rings (two or more) electrically coupled to branch 22. According to a further alternative the single electrode 35 may be defined by a plate conductive element attached to a rigid portion, such as a cassette, of the venous branch.

[0020] In electrical terms, the ring 35 forms a first plate of a capacitor, the PVC tube forms the dielectric, and the blood within the PVC tube forms the second plate. In other words, a capacitive coupling is formed between the branch 22 and the venous branch 10.

[0021] During the dialysis treatment, in other words when the blood is circulating in the extracorporeal circuit 2 between the arterial needle 12 and the venous needle 13, the device 14 is activated by connecting the patient P to earth and setting the selector 24 to the position indicated by A in the attached figure.

[0022] The voltage generated across the secondary 21 of the transformer is 100 Vpp, with a frequency of 35 kHz. An electrical current therefore flows along a closed-loop path P1 of a circuit 37 formed, in succession, by the secondary 21 of the transformer, the branch 22, a portion of the venous branch 10 lying between the electrode 34 and the venous needle 13, the patient P and the branch 23. The path P1 of the current along the circuit 37 is determined by the fact that the impedances Z1 and Z2

are much higher than the impedance Z3, and consequently the currents flowing in the only alternative paths, in which the impedances Z1 and Z2 are located, are negligible.

[0023] The applicant has found that, even if the patient P is not connected to earth, the patient P and the earth act as the opposing plates of a capacitor, and in fact the current flowing along the path P1 is not significantly affected by the connection or non-connection of the patient P to earth. This behaviour is obtained by using an alternating current at a high frequency, of more than 10 kHz in all cases.

[0024] Therefore, both in the condition in which the patient is connected to earth and in the condition in which the patient is not connected to earth, the sensor 17 detects a voltage signal across the terminals of the impedance Z3 and transmits the signal to the unit 15. The voltage signal is a sinusoidal wave which is converted to a square wave by the rectifier 27 and from which is extracted the mean value of voltage in the unit 28. A reference value is subtracted from the mean voltage in the adder 29. The resulting signal is filtered by the filter 30, which has the function of eliminating the signal variations which are slow (less than one per second) and caused by the fluctuations of the blood conductivity. In practice, the filter 30 is used to detect only the abrupt variations of voltage due to the detachment of the venous needle 13, in other words the opening of the circuit 37.

[0025] The filtered signal is compared with a threshold value in the comparison unit 31. Until the filtered signal is below a threshold value (the condition in which the venous needle 13 is connected), the comparator 31 sends a reset signal to the integrator 32, forcing the output of the integrator 32 to zero. The output signal from the integrator 32 is compared with a threshold value in the comparison unit 33, which supplies a control signal equal to zero at its output when the input signal is below the threshold value. When the filtered signal exceeds the threshold value in the comparator 31, the integrator 32 begins to integrate a constant value and sends a time-proportional output signal in such a way that the output signal from the integrator 32 exceeds the threshold value of the comparison unit 33 and the output control signal from the comparison unit 33 takes a positive value.

[0026] The output control signal from the control unit 15 is identical, for practical purposes, to the output signal from the comparison unit 33, and is transmitted to the control unit 34, which, when the control signal takes a positive value, executes a series of actions designed to prevent blood loss, such as stopping the peristaltic pump 9.

[0027] Before the start of the dialysis treatment and during the dialysis treatment, the device 14 is tested by a procedure for determining the functionality of the elements of the device 14. According to this procedure, the selector 24 is set to the position B in such a way as to form a closed circuit formed solely by the secondary of the transformer and the branches 22, 23 and 25, and

current is supplied along the branch 25. The impedance Z4 is equal to the total impedance of the portion of the venous branch 10 and the patient P in the condition in which the venous needle 13 is connected. The generator 16 supplies the transformer 19 with the same voltage as that used during the dialysis treatment, and the voltage signal which is detected across the terminals of the impedance Z3 is processed by the unit 15. The selector 24 is then set to the position C in such a way as to form a closed-loop circuit formed by the secondary 21 of the transformer and the branches 22, 23 and 26. The impedance Z5 is equal to the total impedance of the portion of the venous branch 10 and the patient P in the condition in which the venous needle 13 is detached.

[0028] In fact, the test procedure simulates the operating conditions of the device 14 in such a way as to determine whether the voltage signals detected across the terminals of Z3 lie within ranges of normality and can identify the transition between the condition in which the venous needle 13 is connected and the condition in which the venous needle 13 is detached.

[0029] A further safety measure for the device 14 consists in stopping the generator 16, during the dialysis treatment, when the mean voltage signal takes values in excess of a threshold value.

[0030] In a variant which is not illustrated, the impedance Z3 and the sensor 17 are located in the branch 22 instead of the branch 23.

[0031] In a further variant which is not illustrated, the branch 23 is not earthed, but is connected directly to the patient P, who is isolated from the earth.

Claims

1. Dialysis machine comprising:

an extracorporeal blood circuit (2) provided with a venous branch (10) connected to a venous needle (13) for accessing the cardiovascular system of a patient (P); and
a device for sensing the detachment of the venous needle, (13) from the patient (P) during an extracorporeal blood treatment, **characterized in that** said device (14) comprises:

an electrical line (21, 22, 23) external to the extracorporeal circuit (2), to form, in combination with a portion of the venous branch (10) and the patient (P), an electrical circuit (37) extending along a closed-loop path (P1), said electrical line (21, 22, 23) comprising a first and a second branch (22, 23) and a voltage source (21) located between the first and the second branch (22, 23), the first branch (22), being in use connected to the venous branch (10) and the second branch (23) being in use connected to the

- earth;
 a sensor (17) interacting with the electrical line (21, 22, 23) to detect a signal correlated with the current flowing in said electrical circuit (37), said sensor (17) being located in the first branch (22) or in the second branch (23); and
 means (15) of processing said signal for sensing the opening of said electrical circuit (37).
2. Dialysis machine comprising:
- an extracorporeal blood circuit (2) provided with a venous branch (10) connected to a venous needle (13) for accessing the cardiovascular system of a patient (P), said patient being isolated from the earth; and
 a device for sensing the detachment of the venous needle (13) from the patient (P) during an extracorporeal blood treatment, **characterized in that** said device (14) comprises:
- an electrical line (21, 22, 23) external to the extracorporeal circuit (2), to form, in combination with a portion of the venous branch (10) and the patient (P), an electrical circuit (37) extending along a closed-loop path (P1), said electrical line (21, 22, 23) comprising a first and a second branch (22, 23) and a voltage source (21) located between the first and the second branch (22, 23), the first branch (22), being in use connected to the venous branch (10) and the second branch (23) being in use connected directly to the patient (P);
 a sensor (17) interacting with the electrical line (21, 22, 23) to detect a signal correlated with the current flowing in said electrical circuit (37), said sensor (17) being located in the first branch (22) or in the second branch (23); and
 means (15) of processing said signal for sensing the opening of said electrical circuit (37).
3. Machine according to Claim 1, **characterized in that** it comprises an alternating voltage generator (16) to supply an alternating current to said electrical circuit (37), the voltage having a relatively high frequency in such a way that the patient (P) and the earth are equivalent to the opposing plates of a capacitor.
4. Machine according to Claim 3, **characterized in that** said voltage has a frequency of more than 10 kHz.
5. Machine according to any one of Claims 1 to 4, **characterized in that** the venous branch (10) extends between a filter (4) and the venous needle (13), the extracorporeal circuit (2) comprising a dropper (11) located in said venous branch (10), said electrical line (21, 22, 23) being connected at a single point to said extracorporeal circuit (2), and said point being located in the venous branch (10) between said dropper (11) and the venous needle (13).
6. Machine according to Claims 1 to 5, **characterized in that** said sensor (17) is a sensor of the voltage across the terminals of an impedance (Z3) located in the second branch (23), said signal being a voltage signal.
7. Machine according to any one of Claims 1 to 6, **characterized in that** said signal processing means (15) comprises a filter (30) for filtering the slow variations of said signal, particularly the variations with a frequency of less than one per second.
8. Machine according to any one of Claims 1 to 7, **characterized in that** it comprises means (24, 25, 26) for testing the efficiency of the electrical line (21, 22, 23) and of the signal processing means (15).
9. Machine according to Claim 8, **characterized in that** the electrical line (21, 22, 23) comprises a selector (24) for disconnecting the electrical line (21, 22, 23) from the venous branch (10) and for selectively connecting said electrical line (21, 22, 23) to a first test impedance (Z4) simulating an operating condition with the venous needle (13) connected, and to a second test impedance (Z5) simulating an operating condition with the venous needle (13) disconnected.
10. Machine according to any one of Claims 1 to 9, **characterized in that** it comprises a capacitive coupling for connecting said electrical line (21, 22, 23) to the venous branch (10).
11. Machine according to Claim 10, **characterized in that** said capacitive coupling comprises an electrode (35) provided with at least a ring (36) placed around said venous branch (10), the ring (36) and the blood corresponding to the plates of a capacitor.
12. Machine according to claim 11, **characterized in that** the capacitive coupling comprises a number of rings placed around the venous branch.
13. Machine according to claim 10, **characterized in that** the venous branch includes a rigid box, made of transparent plastic material, the capacitive coupling comprising an electrode (35) defined by a plate conductive element placed in contact with said rigid

box.

Patentansprüche

1. Dialysemaschine umfassend:

einen extrakorporalen Blutkreislauf (2) mit einem venösen Zweig (10), der mit einer venösen Nadel (13) zum Zugang ins Herz-Gefäß-System eines Patienten (P) verbunden ist; und eine Vorrichtung zur Erfassung der Abtrennung der venösen Nadel (13) vom Patienten (P) bei einer extrakorporalen Blutbehandlung, **dadurch gekennzeichnet, daß** diese Vorrichtung (14):

eine elektrische Leitung (21, 22, 23) außerhalb des extrakorporalen Kreislaufs (2) zur Bildung in Kombination mit einem Abschnitt des venösen Zweigs (10) und dem Patienten (P) von einem elektrischen Kreis (37), der sich entlang einem geschlossenen Wirkungsweg (P1) erstreckt, wobei die elektrische Leitung (21, 22, 23) einen ersten und einen zweiten Zweig (22, 23) sowie eine Spannungsquelle (21) umfasst, die zwischen dem ersten und dem zweiten Zweig (22, 23) liegt, wobei der erste Zweig (22) beim Einsatz mit dem venösen Zweig (10) verbunden ist und der zweite Zweig (23) beim Einsatz an die Erde angeschlossen ist; einen Sensor (17), der mit der elektrischen Leitung (21, 22, 23) zur Erfassung eines vom im elektrischen Kreis (37) fließenden Strom abhängigen Signals zusammenwirkt, wobei der Sensor (17) im ersten Zweig (22) oder im zweiten Zweig (23) liegt; und Mittel (15) zur Verarbeitung dieses Signals zur Erfassung des Öffnens des elektrischen Kreises (37),

umfasst.

2. Dialysemaschine umfassend:

einen extrakorporalen Blutkreislauf (2) mit einem venösen Zweig (10), der mit einer venösen Nadel (13) zum Zugang ins Herz-Gefäß-System eines Patienten (P) verbunden ist, wobei der Patient aus der Erde isoliert ist; und eine Vorrichtung zur Erfassung der Abtrennung der venösen Nadel (13) vom Patienten (P) bei einer extrakorporalen Blutbehandlung, **dadurch gekennzeichnet, daß** diese Vorrichtung (14):

eine elektrische Leitung (21, 22, 23) außerhalb des extrakorporalen Kreislaufs (2) zur Bildung in Kombination mit einem Abschnitt des venösen Zweigs (10) und dem Patienten (P) von einem elektrischen Kreis (37), der sich entlang einem geschlossenen Wirkungsweg (P1) erstreckt, wobei die elektrische Leitung (21, 22, 23) einen ersten und einen zweiten Zweig (22, 23) sowie eine Spannungsquelle (21) umfasst, die zwischen dem ersten und dem zweiten Zweig (22, 23) liegt, wobei der erste Zweig (22) beim Einsatz mit dem venösen Zweig (10) verbunden ist und der zweite Zweig (23) beim Einsatz unmittelbar mit dem Patienten (P) verbunden ist; einen Sensor (17), der mit der elektrischen Leitung (21, 22, 23) zur Erfassung eines vom im elektrischen Kreis (37) fließenden Strom abhängigen Signals zusammenwirkt, wobei der Sensor (17) im ersten Zweig (22) oder im zweiten Zweig (23) liegt; und Mittel (15) zur Verarbeitung dieses Signals zur Erfassung des Öffnens des elektrischen Kreises (37),

umfasst.

3. Maschine nach Anspruch 1, **dadurch gekennzeichnet, daß** sie einen Wechselspannungsgenerator (16) zur Zuführung eines Wechselstroms zum elektrischen Kreis (37) umfasst, wobei die Spannung eine relativ hohe Frequenz aufweist, so daß der Patient (P) und die Erde den entgegengesetzten Platten eines Kondensators entsprechen.
4. Maschine nach Anspruch 3, **dadurch gekennzeichnet, daß** die Spannung eine Frequenz über 10 kHz aufweist.
5. Maschine nach irgendeinem der Ansprüche 1 bis 4, **dadurch gekennzeichnet, daß** der venöse Zweig (10) sich zwischen einem Filter (4) und der venösen Nadel (13) erstreckt, wobei der extrakorporale Kreislauf (2) eine Luftblase Falle (11) umfasst, die im venösen Zweig (10) liegt, wobei die elektrische Leitung (21, 22, 23) an einer Einzelstelle mit dem extrakorporalen Kreislauf (2) verbunden ist, und wobei diese Stelle im venösen Zweig (10) zwischen der Luftblase Falle (11) und der venösen Nadel (13) liegt.
6. Maschine nach den Ansprüchen 1 bis 5, **dadurch gekennzeichnet, daß** der Sensor (17) ein Sensor der Spannung durch die Endverschlüsse einer im zweiten Zweig (23) liegenden Impedanz (Z3), wobei das Signal ein Spannungssignal ist.

7. Maschine nach irgendeinem der Ansprüche 1 bis 6, **dadurch gekennzeichnet, daß** die Signalverarbeitungsmittel (15) einen Filter (30) zur Filtration der langsamen Veränderungen des Signals umfassen, insbesondere der Veränderungen mit einer Frequenz unter einer pro Sekunde. 5
8. Maschine nach irgendeinem der Ansprüche 1 bis 7, **dadurch gekennzeichnet, daß** sie Mittel (24, 25, 26) zur Prüfung der Leistungsfähigkeit der elektrischen Leitung (21, 22, 23) und der Signalverarbeitungsmittel (15) umfasst. 10
9. Maschine nach Anspruch 8, **dadurch gekennzeichnet, daß** die elektrische Leitung (21, 22, 23) einen Wählschalter (24) zur Abtrennung der elektrischen Leitung (21, 22, 23) vom venösen Zweig (10) und zur selektiven Verbindung der elektrischen Leitung (21, 22, 23) mit einer ersten Prüfimpedanz (Z4), die eine Betriebsbedingung, bei der die venöse Nadel (13) verbunden ist, simuliert, und mit einer zweiten Prüfimpedanz (Z5), die eine Betriebsbedingung, bei der die venöse Nadel (13) abgetrennt ist, simuliert, umfasst. 15 20 25
10. Maschine nach irgendeinem der Ansprüche 1 bis 9, **dadurch gekennzeichnet, daß** sie eine kapazitive Kupplung zur Verbindung der elektrischen Leitung (21, 22, 23) mit dem venösen Zweig (10) umfasst. 30
11. Maschine nach Anspruch 10, **dadurch gekennzeichnet, daß** die kapazitive Kupplung eine Elektrode (35) mit mindestens einem Ring (36) umfasst, der um den venösen Zweig (10) angeordnet ist, wobei der Ring (36) und das Blut den Platten eines Kondensators entsprechen. 35
12. Maschine nach Anspruch 11, **dadurch gekennzeichnet, daß** die kapazitive Kupplung eine Anzahl von um den venösen Zweig angeordneten Ringen umfasst. 40
13. Maschine nach Anspruch 10, **dadurch gekennzeichnet, daß** der venöse Zweig einen steifen Kasten aus durchsichtigem Kunststoff umfasst, wobei die kapazitive Kupplung eine Elektrode (35) umfasst, die durch ein leitfähiges Plattenelement in Berührung mit dem steifen Kasten definiert ist. 45 50

Revendications

1. Machine de dialyse comprenant:

un circuit extracorporel de sang (2) muni d'une ramification veineuse (10) reliée à une aiguille veineuse (13) pour l'accès au système cardiovasculaire d'un patient (P); et 55

un dispositif pour détecter le détachement de l'aiguille veineuse (13) du patient (P) pendant un traitement extracorporel de sang, **caractérisée en ce que** ledit dispositif (14) comprend:

une ligne électrique (21, 22, 23) externe au circuit extracorporel (2) pour former, en combinaison avec une portion de la ramification veineuse (10) et le patient (P), un circuit électrique (37) s'étendant le long d'un parcours annulaire fermé (P1), ladite ligne électrique (21, 22, 23) comprenant une première et une deuxième ramification (22, 23) et une source de tension (21) placée entre la première et la deuxième ramification (22, 23), la première ramification (22) étant reliée pendant l'usage à la ramification veineuse (10) et la deuxième ramification (23) étant reliée pendant l'usage à la terre; un senseur (17) interagissant avec la ligne électrique (21, 22, 23) pour détecter un signal lié au courant qui s'écoule dans ledit circuit électrique (37), ledit senseur (17) étant placé dans la première ramification (22) ou dans la deuxième ramification (23); et des moyens (15) d'élaboration dudit signal pour détecter l'ouverture dudit circuit électrique (37).

2. Machine de dialyse comprenant:

un circuit extracorporel de sang (2) muni d'une ramification veineuse (10) reliée à une aiguille veineuse (13) pour l'accès au système cardiovasculaire d'un patient (P), ledit patient étant isolé de la terre; et un dispositif pour détecter le détachement de l'aiguille veineuse (13) du patient (P) pendant un traitement extracorporel de sang, **caractérisée en ce que** ledit dispositif (14) comprend:

une ligne électrique (21, 22, 23) externe au circuit extracorporel (2) pour former, en combinaison avec une portion de la ramification veineuse (10) et le patient (P), un circuit électrique (37) s'étendant le long d'un parcours annulaire fermé (P1), ladite ligne électrique (21, 22, 23) comprenant une première et une deuxième ramification (22, 23) et une source de tension (21) placée entre la première et la deuxième ramification (22, 23), la première ramification (22) étant reliée pendant l'usage à la ramification veineuse (10) et la deuxième ramification (23) étant reliée pendant l'usage directement au patient (P); un senseur (17) interagissant avec la ligne

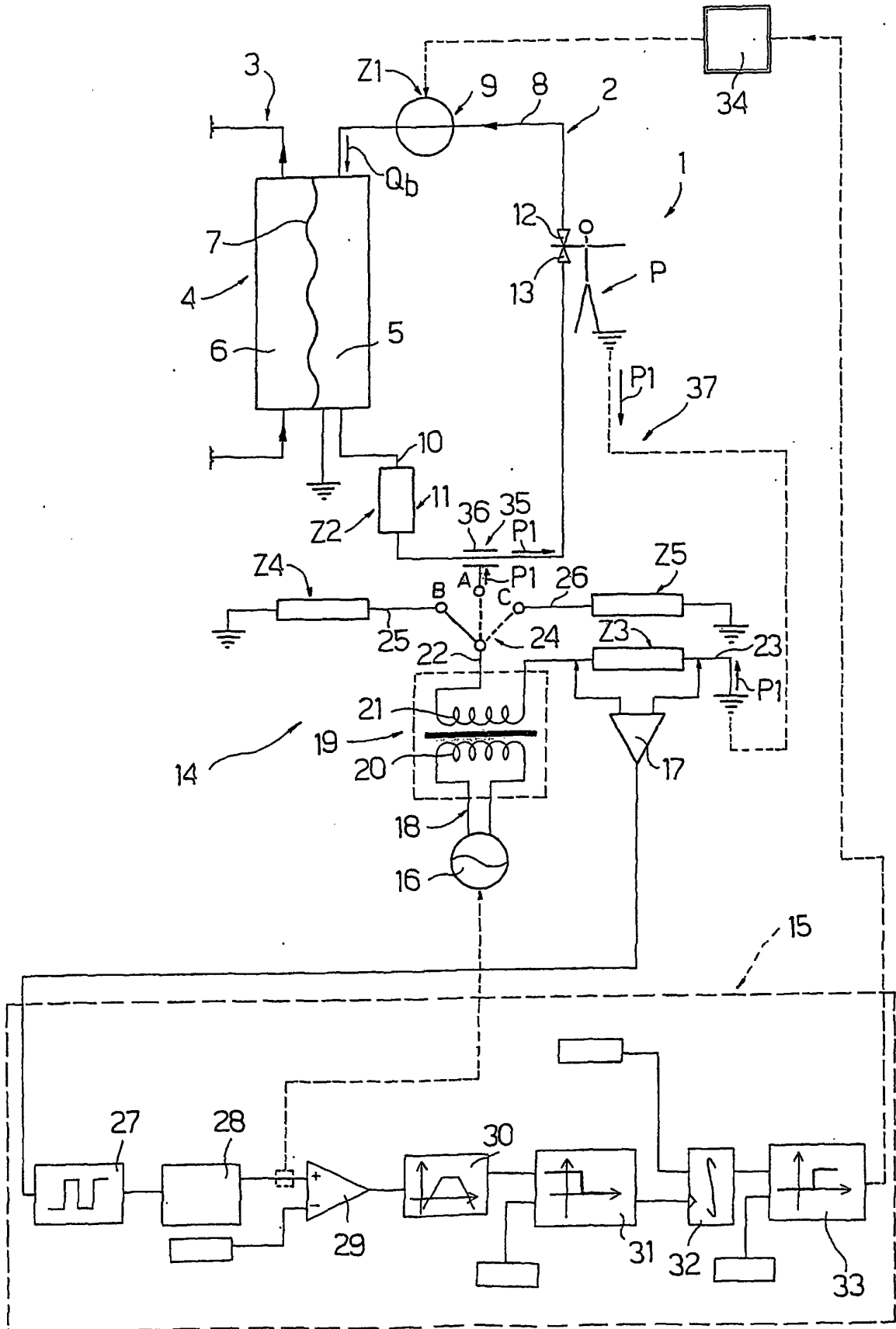
électrique (21, 22, 23) pour détecter un signal lié au courant qui s'écoule dans ledit circuit électrique (37), ledit senseur (17) étant placé dans la première ramification (22) ou dans la deuxième ramification (23); et

des moyens (15) d'élaboration dudit signal pour détecter l'ouverture dudit circuit électrique (37).

3. Machine selon la revendication 1, **caractérisée en ce que** elle comprend un générateur de tension alternée (16) pour alimenter avec un courant alterné ledit circuit électrique (37), la tension ayant une fréquence relativement élevée, de sorte que le patient (P) et la terre correspondent aux plaques opposées d'un condensateur. 5
4. Machine selon la revendication 3, **caractérisée en ce que** ladite tension a une fréquence supérieure à 10 kHz. 10
5. Machine selon l'une quelconque des revendications 1 à 4, **caractérisée en ce que** la ramification veineuse (10) s'étend entre un filtre (4) et l'aiguille veineuse (13), le circuit extracorporel (2) comprenant un piège-à-bulle (11) placée dans ladite ramification veineuse (10), ladite ligne électrique (21, 22, 23) étant reliée dans un seul point audit circuit extracorporel (2), et ledit point étant placé dans la ramification veineuse (10) entre ledit piège-à-bulle (11) et l'aiguille veineuse (13). 15
6. Machine selon les revendications 1 à 5, **caractérisée en ce que** ledit senseur (17) est un senseur de la tension à travers les bornes d'une impédance (Z3) placée dans la deuxième ramification (23), ledit signal étant un signal de tension. 20
7. Machine selon l'une quelconque des revendications 1 à 6, **caractérisée en ce que** lesdits moyens d'élaboration du signal (15) comprennent un filtre (30) pour filtrer les lentes variations dudit signal, notamment les variations ayant une fréquence inférieure à une par seconde. 25
8. Machine selon l'une quelconque des revendications 1 à 7, **caractérisée en ce que** elle comprend des moyens (24, 25, 26) pour vérifier le bon fonctionnement de la ligne électrique (21, 22, 23) et des moyens d'élaboration du signal (15). 30
9. Machine selon la revendication 8, **caractérisée en ce que** la ligne électrique (21, 22, 23) comprend un sélecteur (24) pour détacher la ligne électrique (21, 22, 23) de la ramification veineuse (10) et pour relier sélectivement ladite ligne électrique (21, 22, 23) à une première impédance de vérification (Z4) simu- 35

lant une condition opérationnelle avec l'aiguille veineuse (13) reliée, et à une deuxième impédance de vérification (Z5) simulant une condition opérationnelle avec l'aiguille veineuse (13) détachée.

10. Machine selon l'une quelconque des revendications 1 à 9, **caractérisée en ce que** elle comprend un couplage capacitif pour relier ladite ligne électrique (21, 22, 23) à la ramification veineuse (10). 40
11. Machine selon la revendication 10, **caractérisée en ce que** ledit couplage capacitif comprend une électrode (35) munie d'au moins une bague (36) placée autour de ladite ramification veineuse (10), la bague (36) et le sang correspondant aux plaques d'un condensateur. 45
12. Machine selon la revendication 11, **caractérisée en ce que** le couplage capacitif comprend un nombre de bagues placées autour de la ramification veineuse. 50
13. Machine selon la revendication 10, **caractérisée en ce que** la ramification veineuse comprend une boîte rigide en plastique transparente, le couplage capacitif comprenant une électrode (35) définie par un élément conducteur en forme de plaque en contact avec ladite boîte rigide. 55



REFERENCES CITED IN THE DESCRIPTION

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